

ATTACHMENT B

REMARKS

By this amendment, Applicants have amended the claims in a manner which further reflects that the present claims are clearly patentable over the cited references. In particular, minor amendments have been made to independent Claims 1 and 14 which reflect that the reagents contact the test sample prior to the time that the test sample is administered to the immunoassay strip for testing, and in addition, Claims 26 and 27 are added which relate to the pre-treatment step to dilute or denature the interferants which may be in the sample, such as disclosed, e.g., at page 1, lines 16-19. In light of these amendments, Applicants submit that the present application has been placed in condition for immediate allowance for the reasons as set forth below.

In the Official Action, the Examiner rejected Claims 12, 13, 24 and 25 under 35 U.S.C. § 112, second paragraph, on the objection that the claims were indefinite as relating to a “generally L-shaped” design. Applicants submit that contrary to the Examiner’s position, the term “generally L-shaped” would be very well known to one skilled in this art, or for any of the other mechanical or related arts. Indeed, as shown in the attachments, the term “generally L-shaped” is commonly used in mechanical and related arts, and this phrase has been repeatedly used in issued patent claims as reflected in the Appendix attached hereto (containing claims from U.S. Patent Nos. 6,540,531, 5,712,759, and 5,755,416). Accordingly, Applicants submit that this term is clear on its face and that the claims would be well understood by one of ordinary skill in this art, and thus the Examiner’s rejection is respectfully traversed and should be withdrawn.

In the Official Action, the Examiner rejected Claims 1-25 as being unpatentable under 35 U.S.C. § 103 over the Wickstead et al. patent (U.S. Pat. No. 6,634,243) in view of the Anderson patent (U.S. Pat. No. 6,267,722). The Examiner conceded that the Wickstead reference lacked a second chamber containing a second reagent as provided in the present claims, but that the Anderson reference could be combined with Wickstead to come up with the present invention. The Examiner's rejection on this basis is respectfully traversed for the reasons as set forth below.

The present invention, as particularly embodied in independent Claims 1 and 14 and their dependent claims, is directed to a lateral flow immunoassay specifically designed to alleviate problems in achieving rapid and highly accurate detection of particular compounds in a test sample, e.g., illegal drugs or other intoxicants, particularly wherein the test sample must be pre-treated in order to obtain the rapid and accurate result which would not otherwise be obtainable. A perfect example of the type of test sample suited for use with the present claimed apparatus is a saliva test sample which is a medium that is very difficult to utilize in rapid and accurate testing using an immunoassay strip. In particular, saliva contains mucins which are a family of large, heavily glycosylated proteins which account for many of the properties of saliva. However, the mucins also act to disrupt the lateral flow necessary to achieve a rapid and accurate test result and greatly restrict both the time it takes for a sample to travel through the immunoassay strip as well as the amount of the target compound in the sample which can travel up the strip and thus be determined by the immunoassay strip.

Because of the problems caused by mucins, certain testing systems recommend long and elaborate procedures for removing mucins prior to testing the sample. What was necessary in the art was the ability, using a single device, to pre-treat a sample

such as saliva with a diluent or other reagent which is capable of breaking down the interferants in a sample, e.g., mucins in saliva, so that these interferants do not restrict the capillary flow of the sample through the test strip, which will result in a rapid test of target compounds in a more accurate manner than heretofore possible.

Accordingly, the invention as claimed in the present application is a completely novel and unobvious device which contains a first chamber which contains a pre-treatment reagent, a second chamber which contains a second reagent, means for contacting a test sample with the first reagent, means for mixing the sample, the first reagent and the second reagent prior to the time the mixture is introduced to the immunoassay test strip which allows the pre-treatment reagent to dilute or denature interferants, e.g., mucins from saliva, which would otherwise obstruct and severely limit the speed and effectiveness in carrying out a rapid immunoassay on-site, such as a saliva test for an employee or prospective employee.

As recognized by the Examiner, such a structure is not disclosed in any prior reference, and a review of the references cited by the Examiner show that these references do not even disclose the specific problem to be solved, the pre-treatment of the test sample in such a manner as to provide a quick and accurate reading, much less disclose or suggest the specific solution as reflected in the presently claimed invention. In particular, the Wickstead patent cited by the Examiner, relates to a sample testing device which does not relate to specific improvements which allow pre-treatment with a first reagent in a first chamber combined with treatment with a second reagent in a second chamber. Indeed, as the Examiner has recognized, there is not second chamber in Wickstead providing a second reagent to treat or incubate the test sample prior to introduction of the sample to the test strip. In fact, there is no second chamber

in Wickstead, and instead of a chamber, a compartment with a hollow space for containing fluids, there is merely a filter and not a chamber for providing a space wherein a second reagent and the first reagent can be retained to incubate the sample. Accordingly, Wickstead discloses a device which is far different than the present device, one which does not contemplate a 2-chamber system wherein two separate pre-treating reagents can be separately or sequentially used to incubate a test sample so as to make that sample, such as saliva, particularly conducive to traveling through a test strip in a rapid manner without loss or disruption to the targeted compound in the test sample. Instead, the filter in the Wickstead patent only acts to further slow the entire process and does not result in the rapid accurate immunoassays that are possible using Applicants' claimed device.

The Anderson et al. patent cited by the Examiner is even further afield than the Wickstead patent and thus cannot be combined in any manner to disclose or suggest Applicants' claimed invention. In fact, the Anderson patent discloses a device which is the opposite of the present device in that there are no chambers per se, and there is no pre-treatment of the test sample using separate reagents which are mixed with the test sample prior to the time that the sample is contacted with the test strip. Instead, as is made clear in Fig. 3 of the Anderson patent, the test sample is applied directly onto the test strip at which point the fluid communication begins, and without the pre-treatment steps as provided by the present invention, a rapid and accurate reading of the test sample will not be obtained.

The Anderson device thus clearly does not disclose or suggest the present immunoassay device wherein a pre-treatment first reagent from a first chamber and a second reagent from a second chamber are mixed with a sample so that the sample

can be incubated and diluted and/or denatured rapidly **before** the test sample is then applied to the immunoassay test strip to give the accurate reading. As such, the Anderson patent cannot be combined with the Wickstead patent to anticipate or make obvious Applicants' present invention, and indeed these patents teach away from the invention because they do not recognize the particular problem solved by the present invention, much less disclose or suggest a solution to that problem.

Accordingly, the Examiner's rejection of Claims 1-25 on the basis of the combination of Wickstead and Anderson, insofar as applied to the claims as amended, is respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

END OF REMARKS